REMARKS

Claims 33, 34, 38, 41, 42, 48, 49, and 54-83 are pending in this application. Claims 41 and 42 have been amended. Support for the amendments is in the specification and claims as filed.

Claim Objections

Claims 41 and 42 have been objected to for lack of antecedent basis for the term "implant." Although Applicants do not necessarily agree with the propriety of the rejection, Claims 41 and 42 have been amended to recite "said device." Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. §103(a) – Gough et al. in view of Picha

Claims 33, 34, 38, 41, 42, and 54-83 have been rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,985,129 to Gough et al. ("Gough '129" or "Gough et al.") in view of U.S. Pat. No. 5,271,736 to Picha ("Picha"). To establish a *prima facie* case of obviousness, three basic criteria must be met: first, the prior art reference (or references when combined) must teach or suggest all the claim limitations; second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; finally, there must be a reasonable expectation of success. *See* M.P.E.P. § 2143. Evidence of unobvious or unexpected advantageous properties can rebut *prima facie* obviousness. No set number of examples of superiority is required. *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987) (Evidence showing that the claimed herbicidal compound was more effective than the closest prior art compound in controlling quackgrass and yellow nutsedge weeds in corn and soybean crops was sufficient to overcome the rejection under 35 U.S.C. 103, even though the specification indicated the claimed compound was an average performer on crops other than corn and soybean).

Claim 34 recites a method of measuring glucose in a biological fluid comprising, *inter alia*, the step of "providing an implantable device comprising ... a housing ... wherein said housing comprises a first portion and a second portion, wherein a curvature of the second portion is greater than a curvature of the first portion; wherein said first domain is located over at least a portion of said protruding second portion ... ." Claim 38 recites a method of monitoring glucose

levels, comprising, *inter alia*, the step of "providing ... a device comprising a housing ... wherein said housing comprises a convexly curved portion over which a sensing membrane and a first domain are located ... ."

Gough '129 disclose an implantable sensor design with a thin, cylindrical shape, which allows "its inclusion in the two-dimensional glucose sensor described in the above-cited patents" (col. 3, lines 44-47); the "above-cited patents" include U.S. Patent No. 4,703,756, which is useful in understanding the sensor system design used for implanting the sensor 2 as illustrated in Fig. 1 (Gough '129). As described by Gough '129, the sensor 2 is made by welding electrodes to one end of a long PTFE-insulated stainless steel lead wire, individually encapsulating ends of the electrodes in the lumens of a short segment of glass tubing, forming an electrolyte gel around the electrodes, and forming an outer hydrophobic layer (col. 8, lines 38-67). Subsequently, the sensor is fixed in a silicone rubber tube in such a way that the lead wires extend inside the tube and the active electrode region occupies one end, which "recessed design presents an annular space around the electrodes which may be filled with an enzyme gel for enzyme electrode applications" (col. 9, lines 1-8). The annular cavity is then either filled with silicone rubber or the tube is trimmed to expose the hydrophobic membrane-covered electrode assembly (col. 9, lines 9-11). U.S. Patent No. 4,703,756 to Gough et al. ("Gough '756"), which is incorporated by reference into Gough '129, illustrates the design described above. Namely, Figs. 1 and 2 of the Gough '756 reference illustrate the same sensor design as Fig. 1 of Gough '129; additionally, Figs. 3-5 of Gough '756 illustrate the tube (e.g., catheter), described by Gough '129, used for implantation of the sensor. Col. 4, lines 1-22 of Gough '756 describe the systems suitable for implantation as illustrated in Figs. 3-5, including a design wherein the sensors are "recessed from the tip of the catheter" (col. 4, line 21), which teaches away from a protruding portion as claimed. Even in the alternative design described above, wherein "the tube is trimmed to expose the hydrophobic membrane-covered electrode assembly," Gough '129 does not teach or fairly suggest a configuration wherein "the hydrophobic membrane-covered electrode assembly" protrudes from the tube.

Picha teaches covering the outside of an implantable sensor device with foam (col. 5, lines 43-48). Accordingly, if one of ordinary skill in the art at the time of the invention were to cover the sensor device of Gough '129 with foam, he would cover the outer silicone tubing in

which the sensor 2 of Gough '129 is fixed (or the housing 14 of the Gough '756 device) with the foam material. Because the sensor of the Gough references does not protrude from the silicone tubing housing, the outer foam material would not be located over a protruding portion having a curvature (or protruding convexly curved portion of the sensor) and including a sensing membrane and angiogenic layer (or vascularization promotion layer) as claimed.

Applicants note that a protruding region that is convexly curved or has a curvature offers advantages over the configurations of the prior art, namely, superior performance in the formation of vasculature in the sensor interface region. The overall curvature of the surface on which the sensing region is located, including rounded edges, invokes a generally uniform foreign body capsule around that surface, decreasing inflammatory response and increasing analyte transport at the device-tissue interface. The curvature ensures that the sensing region is resting against the tissue and that when tissue contraction occurs, forces are generated downward on the sensing region so that the tissue attachment is maintained. The downward forces bring the tissue into contact with porous biointerface materials used for ingrowth-mediated attachment and for biointerface optimization. Accordingly, the curvature of the sensing region, not just its protrusion, is important to the process of vascularization.

Because neither Gough et al. nor Picha, alone or in combination, disclose a protruding portion having a curvature (or protruding convexly curved portion)and including a sensing membrane and angiogenic layer (or vascularization promotion layer) as claimed, and because Applicants' protruding convexly curved portion (or a protruding portion having a curvature) is responsible for superior vascularization above the sensing membrane when compared to prior art configurations, Applicants respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. §103(a) – Gough et al. in view of Picha and Gilligan et al.

Claims 48 and 49 have been rejected under 35 U.S.C. §103(a) as obvious over Gough et al. in view of Picha and further in view of Gilligan et al. ("Evaluation of a Subcutaneous Glucose Sensor out to 3 Months in a Dog Model," Diabetes Care, Vol. 17, No. 8, August 1994, page 882). To establish a *prima facie* case of obviousness, the prior art references must teach or suggest all the claim limitations. *See* M.P.E.P. § 2143.

Claim 48 depends from Claim 34 and Claim 49 depends from Claim 38. As discussed above, Claim 34 recites a method of measuring glucose in a biological fluid comprising, *inter*

alia, the step of "providing an implantable device comprising ... a housing ... wherein said housing comprises a first portion and a second portion, wherein a curvature of the second portion is greater than a curvature of the first portion; wherein said first domain is located over at least a portion of said protruding second portion ... ." Claim 38 recites a method of monitoring glucose levels, comprising, *inter alia*, the step of "providing ... a device comprising a housing ... wherein said housing comprises a convexly curved portion over which a sensing membrane and a first domain are located ... ."

Gilligan et al. is cited for teaching use of an enzyme membrane. Gilligan et al. does not teach a protruding portion having a curvature (or protruding convexly curved portion) and including a sensing membrane and angiogenic layer (or vascularization promotion layer) as claimed, and thus does not overcome the deficiencies of Gough et al. and Picha. Applicants therefore respectfully request withdrawal of the rejection.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw to the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
07/216683	BIOLOGICAL FLUID MEASURING DEVICE	July 7, 1988
08/811473	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	March 4, 1997
09/489588	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	January 21, 2000

09/636369	SYSTEMS AND METHODS FOR REMOTE MONITORING AND MODULATION OF MEDICAL DEVICES	August 11, 2000
09/916386	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	July 27, 2001
09/916858	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	July 27, 2001
10/153356	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	May 22, 2002
10/632537	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	August 1, 2003
10/633329	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	August 1, 2003
10/633367	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	August 1, 2003
10/633404	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	August 1, 2003
10/646333	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	August 22, 2003
10/647065	POROUS MEMBRANES FOR USE WITH IMPLANTABLE DEVICES	August 22, 2003
10/648849	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	August 22, 2003
10/657843	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	September 9, 2003
10/768889	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	January 29, 2004
10/789359	INTEGRATED DELIVERY DEVICE FOR CONTINUOUS GLUCOSE SENSOR	February 26, 2004
10/838658	IMPLANTABLE ANALYTE SENSOR	May 3, 2004
10/838909	IMPLANTABLE ANALYTE SENSOR	May 3, 2004
10/838912	IMPLANTABLE ANALYTE SENSOR	May 3, 2004
10/842716	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	May 10, 2004
10/846150	ANALYTE MEASURING DEVICE	May 14, 2004
10/885476	SYSTEMS AND METHODS FOR MANUFACTURE OF AN ANALYTE-MEASURING DEVICE INCLUDING A MEMBRANE SYSTEM	July 6, 2004
10/896637	ROLLED ELECTRODE ARRAY AND ITS METHOD FOR MANUFACTURE	July 21, 2004

10/896639	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	July 21, 2004
10/897312	ELECTRODE SYSTEMS FOR ELECTROCHEMICAL SENSORS	July 21, 2004
10/897377	ELECTROCHEMICAL SENSORS INCLUDING ELECTRODE SYSTEMS WITH INCREASED OXYGEN GENERATION	July 21, 2004
10/991353	AFFINITY DOMAIN FOR ANALYTE SENSOR	November 16, 2004
10/991966	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	November 17, 2004
11/004561	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	December 3, 2004
11/007635	SYSTEMS AND METHODS FOR IMPROVING ELECTROCHEMICAL ANALYTE SENSORS	December 7, 2004
11/007920	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	December 8, 2004
11/021046	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	December 22, 2004
11/021162	SENSOR HEAD FOR USE WITH IMPLANTABLE DEVICES	December 22, 2004
11/034343	COMPOSITE MATERIAL FOR IMPLANTABLE DEVICE	January 11, 2005
11/034344	IMPLANTABLE DEVICE WITH IMPROVED RADIO FREQUENCY CAPABILITIES	January 11, 2005
11/038340	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	January 18, 2005
11/039269	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	January 19, 2005
11/055779	BIOINTERFACE WITH MACRO-AND MICRO-ARCHITECTURE	February 9, 2005
11/077643	TRANSCUTANEOUS ANALYTE SENSOR	March 10, 2005
11/077693	TRANSCUTANEOUS ANALYTE SENSOR	March 10, 2005
11/077713	TRANSCUTANEOUS ANALYTE SENSOR	March 10, 2005
11/077714	TRANSCUTANEOUS ANALYTE SENSOR	March 10, 2005
11/077715	TRANSCUTANEOUS ANALYTE SENSOR	March 10, 2005
11/077739	TRANSCUTANEOUS ANALYTE SENSOR	March 10, 2005
11/077740	TRANSCUTANEOUS ANALYTE SENSOR	March 10, 2005
11/077759	TRANSCUTANEOUS MEDICAL DEVICE WITH VARIABLE STIFFNESS	March 10, 2005
11/077763	METHOD AND SYSTEMS FOR INSERTING A TRANSCUTANEOUS ANALYTE SENSOR	March 10, 2005

11/077765	TRANSCUTANEOUS ANALYTE SENSOR	March 10, 2005
11/077883	TRANSCUTANEOUS ANALYTE SENSOR	March 10, 2005
11/078072	TRANSCUTANEOUS ANALYTE SENSOR	March 10, 2005
11/078230	TRANSCUTANEOUS ANALYTE SENSOR	March 10, 2005
11/078232	TRANSCUTANEOUS ANALYTE SENSOR	March 10, 2005
11/157365	TRANSCUTANEOUS ANALYTE SENSOR	June 21, 2005
11/157746	TRANSCUTANEOUS ANALYTE SENSOR	June 21, 2005
11/158227	TRANSCUTANEOUS ANALYTE SENSOR	June 21, 2005
11/201445	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	August 10, 2005
11/280102	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	November 16, 2005
11/280672	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	November 16, 2005
11/333837	LOW OXYGEN IN VIVO ANALYTE SENSOR	January 17, 2006
11/334876	TRANSCUTANEOUS ANALYTE SENSOR	January 18, 2006
11/335879	CELLULOSIC-BASED INTERFERENCE DOMAIN FOR AN ANALYTE SENSOR	January 18, 2006
11/360250	ANALYTE SENSOR	February 22, 2006
11/360252	ANALYTE SENSOR	February 22, 2006
11/360262	ANALYTE SENSOR	February 22, 2006
11/360299	ANALYTE SENSOR	February 22, 2006
11/360819	ANALYTE SENSOR	February 22, 2006
11/373628	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION	March 9, 2006
11/404417	SILICONE BASED MEMBRANES FOR USE IN IMPLANTABLE GLUCOSE SENSORS	April 14, 2006
11/404418	SILICONE BASED MEMBRANES FOR USE IN IMPLANTABLE GLUCOSE SENSORS	April 14, 2006
11/404421	ANALYTE SENSING BIOINTERFACE	April 14, 2006
11/404929	ANALYTE SENSING BIOINTERFACE	April 14, 2006
11/404946	ANALYTE SENSING BIOINTERFACE	April 14, 2006
11/410392	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	April 25, 2006
11/410555	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	April 25, 2006

11/411656	ANALYTE SENSOR	April 26, 2006
11/413238	CELLULOSIC-BASED RESISTANCE DOMAIN FOR AN ANALYTE SENSOR	April 28, 2006
11/413242	CELLULOSIC-BASED RESISTANCE DOMAIN FOR AN ANALYTE SENSOR	April 28, 2006
11/413356	CELLULOSIC-BASED RESISTANCE DOMAIN FOR AN ANALYTE SENSOR	April 28, 2006
11/415593	TRANSCUTANEOUS ANALYTE SENSOR	May 2, 2006
11/415631	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	May 2, 2006
11/415999	TRANSCUTANEOUS ANALYTE SENSOR	May 2, 2006
11/416058	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	May 2, 2006
11/416346	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	May 2, 2006
11/416375	TRANSCUTANEOUS ANALYTE SENSOR	May 2, 2006
11/416734	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	May 3, 2006
11/416825	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	May 3, 2006
11/439559	ANALYTE SENSOR	May 23, 2006
11/439630	ANALYTE SENSOR	May 23, 2006
11/439800	ANALYTE SENSOR	May 23, 2006
11/445792	ANALYTE SENSOR	June 1, 2006
11/498410	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	August 2, 2006
11/503367	ANALYTE SENSOR	August 10, 2006
11/515342	SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	September 1, 2006
11/515443	SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	September 1, 2006
11/543396	ANALYTE SENSOR	October 4, 2006
11/543404	ANALYTE SENSOR	October 4, 2006
11/543490	ANALYTE SENSOR	October 4, 2006
11/543539	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	October 4, 2006
11/543683	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	October 4, 2006
11/543707	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	October 4, 2006

11/543734	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	October 4, 2006
11/546157	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	October 10, 2006
11/654135	POROUS MEMBRANES FOR USE WITH IMPLANTABLE DEVICES	January 17, 2007
11/654140	MEMBRANES FOR AN ANALYTE SENSOR	January 17, 2007
11/654327	MEMBRANES FOR AN ANALYTE SENSOR	January 17, 2007
11/675063	ANALYTE SENSOR	February 14, 2007
11/681145	ANALYTE SENSOR	March 1, 2007
11/690752	TRANSCUTANEOUS ANALYTE SENSOR	March 23, 2007
11/691424	ANALYTE SENSOR	March 26, 2007
11/691426	ANALYTE SENSOR	March 26, 2007
11/691432	ANALYTE SENSOR	March 26, 2007
11/691466	ANALYTE SENSOR	March 26, 2007
11/692154	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	March 27, 2007
11/734178	TRANSCUTANEOUS ANALYTE SENSOR	April 11, 2007
11/734184	TRANSCUTANEOUS ANALYTE SENSOR	April 11, 2007
11/734203	TRANSCUTANEOUS ANALYTE SENSOR	April 11, 2007
11/750907	ANALYTE SENSORS HAVING A SIGNAL-TO-NOISE RATIO SUBSTANTIALLY UNAFFECTED BY NON-CONSTANT NOISE	May 18, 2007
11/762638	SYSTEMS AND METHODS FOR REPLACING SIGNAL DATA ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	June 13, 2007
11/763215	SILICONE COMPOSITION FOR BIOCOMPATIBLE MEMBRANE	June 14, 2007
11/797520	TRANSCUTANEOUS ANALYTE SENSOR	May 3, 2007
11/797521	TRANSCUTANEOUS ANALYTE SENSOR	May 3, 2007
11/842142	TRANSCUTANEOUS ANALYTE SENSOR	August 21, 2007
11/842143	TRANSCUTANEOUS ANALYTE SENSOR	August 20, 2007
11/842146	ANALYTE SENSOR	August 20, 2007
11/842148	TRANSCUTANEOUS ANALYTE SENSOR	August 21, 2007
11/842149	TRANCUTANEOUS ANALYTE SENSOR	August 21, 2007
11/842151	ANALYTE SENSOR	August 21, 2007
11/842154	TRANSCUTANEOUS ANALYTE SENSOR	August 20, 2007

11/842156	ANALYTE SENSORS HAVING A SIGNAL-TO-NOISE RATIO SUBSTANTIALLY UNAFFECTED BY NON-CONSTANT NOISE	August 21, 2007
11/842157	ANALYTE SENSOR	August 21, 2007
11/855101	TRANSCUTANEOUS ANALYTE SENSOR	September 13, 2007
60/942787	INTEGRATED DELIVERY DEVICE FOR CONTINUOUS GLUCOSE SENSOR	June 8, 2007

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 9/14/07

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